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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SHIBUYA, MARK LANCE

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/074,745

Applicant(s)

SCHULTZ ET AL.

Examiner

Mark Shibuya

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 94,96-121,124 and 127-170 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 94,96-103,106,107,112,115,116,121,124,127,129-145,151,152,158,163-165 is/are rejected.
- 7) ☒ Claim(s) 166-170 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 104,105,108-111,113,114,117-120,128,146-150,153-157,159-162 and 166-170.

DETAILED ACTION

1. Applicant's Response to the previous Office action and claims filed 10/09/2003, and the claims filed 1/12/2004 are acknowledged. In the claims filed 10/09/2003, claims 164-170 also were added. Therefore, claims 94, 96-121, 124, 127-170 are pending currently.
2. Claims 104, 105, 108-111, 113, 114, 117-120, 128, 146-150, 153-157, 159-162 remain withdrawn from further consideration by the examiner 37 CFR 1.142(b), as being drawn to non-elected species, there being no allowable generic claim. Applicant is reminded that **only** upon the allowance of a generic claim are they entitled to consideration of claims to additional species that are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. See previous action and election of species requirements for discussion of non-elected species claims.
3. Therefore, claims 94, 96-103, 106, 107, 112, 115, 116, 121, 124, 127, 129-145, 151, 152, 158, and 163-165 are examined on the merits in the instant action. Claims 166-170 are objected to and withdrawn from consideration (please see the below Claim Objections).
4. The submission of the Declaration of Adam L. Safir under 37 C.F.R §1.132, filed 2/13/2004, (hereinafter Safir Declaration) is acknowledged.

Claim Objections

5. Claims 166-170 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. Claims 166-170 recite the language "[t]he method of claims 94, 127 and 135." See MPEP § 608.01(n). Accordingly, the claims 166-170 have not been further treated on the merits. This objection is necessitated by applicant's amendment to the claims, filed 10/9/2003, wherein said claims 166-170 were newly added.

Claim Rejections - 35 USC § 112, First Paragraph

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 163 and newly added claims 164 and 165, which depend from claim 163, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. This rejection maintains the reasons of record for rejection of claim 163, as set forth in the previous Office action, mailed 4/9/2003. Applicant's amendment, filed 10/9/2003, adding new claims 164 and 165, both of which depend from claim 163, necessitates the rejection of claims 164 and 165 under the instant rejection.

Response to Arguments

8. Applicant's arguments filed 10/02/2003 have been fully considered but they are not persuasive.

9. Applicant, in the response filed 10/9/2003, at pp. 16-19, points to various parts of the specification for support for the preparation and use of arrays to synthesize copolymers. Applicant argues that "each of the specific features recited in the claim are *expressly disclosed* in the specification, and a person of ordinary skill in the art would have understood Applicants considered their invention of include the combination of such feature." Response filed 10/9/2003.

10. However, applicant does not point, with particularity, to where support in the specification may be found for the delivering components to a third, fourth, fifth, sixth, seventh, eighth, ninth, and tenth region or for a third, fourth, fifth, sixth, seventh, eighth, ninth, and tenth polymer. The lack of support for these specific combinations is made prominent by the limitation recited in claim 163, and its dependent claims, for "ten or more non-biological organic polymers" (emphasis added). It appears that the specification does not contemplate explicitly, for example, a "third" or a "fourth" or a "ninth" or a "tenth region" or a "third" or a "fourth" or a "ninth" "tenth polycarbonate polymer", etc., and does not provide explicit support for making more than ten regions or polymers. Even instantly rejected claim 163, itself, does not recite specific steps for making more than ten polymers. As stated in the previous Office action, "a broad generic disclosure is **not** sufficient support for a specific entity within the class".

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11. Therefore, because applicant has not pointed, with particularity, where support may be found in the specification for, the instant rejection is maintained.

12. In the previous Office action, mailed 4/9/2003, claims 94-103, 106, 107, 112, 115, 116, 121, 123, 124, 126, 127, 129-145, 151, 152, 158 and 163 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This rejection is withdrawn.

13. Applicant's arguments, see pp. 15-23 of the response, filed 10/9/2003, with respect to the instant rejection under written have been fully considered and are persuasive. The instant written description rejection under 35 U.S.C. 112, first paragraph, of claims has been withdrawn.

14. Claims 94, 96-103, 106, 107, 112, 115, 116, 121, 124, 127, 129-145, 151, 152, 158, 163-165 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for arrays of polymers formed by polymerization of styrene with acrylonitrile and screening such arrays for a physical property, does not reasonably provide enablement for making an array of any type of "non-biological organic polymers" and screening the array for any "property of interest" as broadly called for in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection maintains the reasons of record for the rejection of claims 94-103, 106, 107, 112, 115, 116, 121, 123,

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124, 126, 127, 129-145, 151, 152, 158, and 163, as set forth in the Office action mailed 4/9/2003. Applicant's amendment, filed 10/9/2003, adding new claims 164 and 165, both of which depend from claim 163, necessitates the rejection of claims 164 and 165 under the instant rejection.

Response to Arguments

15. Applicant's arguments filed 10/9/2003 have been fully considered but they are not persuasive.

16. In applicant's response to the previous Office action, applicant asserts that the previous Office action misapplied many of the factor set forth in In re Wands, and that a person of skill in the art would have been able to practice the claimed invention without undue experimentation. Applicant asserts that a person of skill in the art would have appreciated that the invention defined by the instant claims relates to a protocol involving a format for preparing and screening arrays of non-biological organic polymers that is completely general to and independent of the particular types of polymerization chemistries (e.g., polymer structures) and polymerization reactions. Applicant argues that concerns relating to the scope of the polymer structure and to the inherent uncertainty of polymerization chemistries and reactions is misplaced in this instance. Applicant states in the repose to the previous Office action that: "In fact, it is the inherent unpredictability in the art that makes Applicants' invention particularly useful – because it provides a protocol and format that offers significant advantages for investigating polymers and polymerization reactions." Response filed 10/9/2003 at p. 24.

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17. Applicant asserts that the specification provides substantial guidance to the defining feature of the invention, as claimed – the preparation of diverse polymeric materials in a spatially addressable, common-substrate format. Applicant asserts the specification discloses techniques particularly suited to delivery of monomers, including techniques for solution-phase monomers, and to the reaction of monomers and “optionally other delivered components.” Response filed 10/9/2003, at pp. 24-25.

18. Applicant asserts that because of the guidance provided by the specification, “especially when coupled with the vast warehouse of knowledge existing in the art related to specific polymerization reactions of interest, a person of ordinary skill would have been enabled to apply Applicants’ teaching to the specific chemistries and reactions of interest without undue experimentation.” Response filed 10/9/2003 at p. 25.

19. In regard to the instant scope of enablement rejection of claim 163, applicant finds it “particularly troubling” that the examiner “appears to suggest that since the structure is alleged to lack descriptive support, that it is likewise not enabled.” Applicant states that the law holds that a claimed invention can be fully enabled, even if, for argument’s sake, the invention lacks support in the specification.

20. The Declaration of Adam L. Safir under 37 C.F.R §1.132, filed 2/13/2004, (hereinafter Safir Declaration) offers Exhibits B, C, D, E, and F to exemplify that the art for polymerization chemistry is well developed. Dr. Safir declares that the manufacture of polymers reported in these Exhibits, did not require undue experimentation. Dr. Safir declares that it is his opinion that a person of ordinary skill in the art would be expected

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to have a Ph.D. in Chemistry. Dr. Safir, at paragraph 22, declares that the nature of the invention is that "it is the inherent unpredictability in the art of polymer structures that makes the invention [of the pending claims] particularly useful – because it provides a protocol and format that offers significant advantages for investigating polymers and polymerization reactions." Safir Declaration at paragraph 22. Dr. Safir states that the specification provides substantial guidance that relates to the particular nature of the invention that applicants are claiming, that the specification also discloses that the arrays of non-biological polymeric materials can be screened according to many specifically-known techniques for specifically-known properties of interest, and that the preparation of an array of non-biological polymers is exemplified in Example B.

21. Applicant's arguments and the Safir Declaration have been fully considered but are not persuasive. Both applicant's arguments and the Safir Declaration explicitly state that the art of polymer preparation is unpredictable. Applicant and the Safir Declaration even argue that the unpredictability of the art is at the source of the particular utility and the nature of the claimed invention. But it is the unpredictability of the art that will limit the usefulness of the claimed invention, because the making and screening of any non-biological organic polymer, as encompassed by breadth of the claims, will at some point require methods and screening that are not routine.

22. Applicant's assertion that the specification provides guidance for techniques suited for monomers and reactions of solution based monomers does not address the direction required for the preparation and assay of any polymer produced from any non-biological polymer. The specification and the Safir Declaration refer to established

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chemistry, but the claimed invention, in making and assaying any polymer, must go beyond firmly established chemistry because the synthetic intermediates can be numerous, structurally complex, in small quantity, and not amenable to routine purification and characterization techniques. In using the claimed invention, one of skill in the art would be constrained to pick and choose the polymers to prepare and the assays with which to study those selected polymers.

23. It is true that level of one of skill in the art is high and that there is a vast prior art for the chemistry of polymers. However, these facts do not serve to render routine the challenging, experimental science of polymer chemistry. As the applicant argues and Dr. Safir declares, polymer chemistry is unpredictable, even for the highly skilled.

24. The correctness of applicant's statement that the enablement and written description requirements are separate under the law of 35 U.S.C. 112, is acknowledged by the examiner. The issue, as applicant reminds us, is whether the specification as filed provides direction and guidance to make and use the claimed invention. As for claim 163, which is drawn to preparing and evaluating ten or more polycarbonate polymers, that requisite guidance and direction is lacking. There is a gap between what the specification teaches, and making and using ten or more polymers in the claimed invention.

25. Therefore, because undue experimentation would be required to make and use the claimed invention in its full scope, the instant rejection is maintained.

Claim Rejections - 35 USC § 112, Second Paragraph

26. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

27. In the previous Office action, claims 94-103, 106, 107, 111, 115 and 116 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is withdrawn.

28. In view of applicant's amendment to claim 94, filed 10/9/2003, the instant rejection is withdrawn. Applicant's arguments, see Office action, filed 10/9/2003, with respect to amended claim 94, replacing the language "of evaluating" with --for preparing-- have been fully considered and are persuasive.

Claim Rejections - 35 USC § 103

29. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

30. In the previous Office action, claims 94-103, 106, 107, 112, 115, 116, 121, 123, 124, 126, 127, 129-145, 151, 152 and 158 were rejected under 35 U.S.C. 103(a) as being unpatentable over Rolleston et al. (US 5,416,613) and Howard et al. (US 3,868,221) in view of Baldeschwieler et al. (US 5,847,105) and Leasure et al. (Inorg.

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Chem. 33(7), 1994) and Gallop et al. (J. Org. Chem. 37(9), 1994). This rejection is withdrawn.

31. In view of applicant's amendment to claim 94, filed 1/12/2004, and in view of applicant's arguments, see Office action, filed 10/9/2003, which have been fully considered and are persuasive, the instant rejection of the claims has been withdrawn.

Conclusion

32. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Shibuya
Examiner
Art Unit 1639


PADMASHRI PONNALURI
PRIMARY EXAMINER
